IFS
Internal Fixation Systems

Internal Fixation Systems, Inc.
510(k) Summary

AUG 13 2007

Company Name:	Internal Fixation Systems, Inc. 10100 N.W. 116th Way Miami, Florida 33178
Contact Name:	Steve Hernandez 10100 N.W. 116th Way Miami, Florida 33178 (305) 216-4766
Trade Name:	IFS Bone Fixation Devices
Common Name:	Bone Fixation Fasteners
Regulation Name:	Smooth or Threaded Metallic Bone Fixation Fastener
Regulation Number:	21 CFR 888.3040
Regulatory Class:	II
Device Product Code:	HWC
Substantially Equivalent Devices:	Depuy Kirschner Wires and Steinmann Pins (K960385) Plus Cancellous Bone Screws (K011719) Biodynamic Technologies, Inc. (K972403) GSO Bone Fixation Fasteners (K063589) Nexa Bone Screw System (K053394) Synthes 3.5 Cortex Screws (K043185) Synthes 7.0/7.3 Cannulated Screws (K962011) OsteoMed 1.2mm Auto-Drive Screw System (K023260)
Device Description:	The IFS Bone Fixation Devices consist of cancellous, malleolar, or cortical screws ranging from 6 to 160mm in length and 1.5mm to 7.3mm in diameter. Threaded, spaded or blunt guide wires range from 0.028 to 0.188 of an inch in diameter and 4 to 12 inches in length. All IFS Bone Fixation

	Devices are manufactured using 316L stainless steel.
Intended Use:	The IFS Bone Fixation Devices are indicated for use in fixation of bone fractures, for bone reconstructions, as guide pins for insertion of other implants or implantation through the skin so that traction may be applied to the skeletal system.
Technological Characteristics Comparison:	The IFS Bone Fixation Devices are substantially equivalent to the predicate devices with respect to design and material.
Sterilization Information:	IFS Bone Fixation Devices will be distributed non-sterile. The devices are sterilized by the end user per the AAMI Guidelines "Good Hospital Practice: Steam Sterilization and Sterility Assurance" and ANSI/AAMI/ISO 11737 guidelines to achieve the Sterility Assurance Level (SAL) of 10^{-6}.
Conclusion:	There are no significant differences between bone fixation devices and the other devices as listed in the Substantially Equivalent Devices. The IFS Bone Fixation Devices and the predicate devices have similar design attributes, material, and intended use thus is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 13 2007

Internal Fixation Systems, Inc.
% Mr. Steve Hernandez
President
10100 NW 116th Way, Ste. 18
Miami, Florida 33178

Re: K071035
Trade/Device Name: IFS Bone Fixation Devices
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: June 19, 2007
Received: June 21, 2007

Dear Mr. Hernandez:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K071035 (pg 1/1)

Indications for Use

510(k) Number (if known):

Device Name: IFS Bone Fixation Devices

Indications for Use: The IFS Bone Fixation Devices are indicated for use in fixation of bone fractures, for bone reconstructions, as guide pins for insertion of other implants or implantation through the skin so that traction may be applied to the skeletal system.

Warning: IFS Bone Fixation Devices are not indicated for spinal fixation.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K071035